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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,033	01/08/2008	Wei-Chiang Shen	89188.0151	5935
73230 7590 06/09/2011				
DLA PIPER US LLP				
1999 AVENUE OF THE STARS				
SUITE 400				
LOS ANGELES, CA 90067-6023				
EXAMINER				
CHANDRA, GYAN				
ART UNIT		PAPER NUMBER		
1646				
NOTIFICATION DATE		DELIVERY MODE		
06/09/2011		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary**Application No.**

10/575,033

Applicant(s)

SHEN ET AL.

Examiner

GYAN CHANDRA

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 8-30 is/are pending in the application.
- 4a) Of the above claim(s) 12-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 8-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/18/2011 has been entered.

Status of Application, Amendments, And/Or Claims

The amendments of claims 1, 8 and 9, and the cancellation of claim 5 have been made of record.

Claims 1 and 8-30 are pending. Claims 12-30 remain withdrawn for the reasons of record on pg. 2 of the Office Action of 12/11/2009.

Claims 1 and 8-11 are under examination.

Response to Arguments

Claim Rejections - 35 USC § 102-withdrawn

The rejection of claims 1 and 9-11 under 35 U.S.C. 102(a) as being anticipated by Widera et al (previously presented, Pharmaceutical Res. 20: 1231-1238, 2003 is withdrawn in view of Applicant's amendments of claim 1. However, upon further consideration a new ground of rejection would be made under 35 USC 103 (a).

Claim Rejections - 35 USC § 103-withdrawn

The rejection of claims 1 and 8 under 35 U.S.C. 103(a) as being unpatentable over Widera et al in view of Prior et al (US Patent No. 7,176,278) is withdrawn in view of Applicants amendments as well as their arguments. However, upon further consideration a new ground of rejection is made under 35 USC 103(a).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 8-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Yeh et al (US Patent No. 5,665,863).

The instant claims are broadly drawn to a fusion polypeptide comprising a granulocyte colony stimulating factor (G-CSF) domain operably linked to a transferring (Tf) domain, wherein the fusion polypeptide is a recombinant polypeptide, wherein the fusion polypeptide further comprises a secretion signal at the N-terminus and wherein Tf binds to two iron molecules.

Yeh et al teach one of the drawbacks of currently available G-CSF lies in that the fact that it is rapidly downgraded by the body once it is administered (col. 1, lines 39+). They teach that this drawback is remedied by making fusion of G-CSF while retaining the affinity of G-CSF for its receptor and still maintaining the biological activity

of G-CSF for sufficiently long time (col. 1, lines51+). They teach making essentially all or an active portion of G-CSF or a variant of G-CSF and an essentially proteinaceous stabilizing structure (col. 2, lines 5+). They teach that the stabilizing structure can be transferrin (col. 2, line 59). They teach that the active molecule can be coupled to the stabilizing structure directly or via a peptide linker and it can constitute at the N-terminus end or the C-terminus end if the molecule (col. 2, lines48+). They teach that making the fusion protein by recombinant technology and that the encoding sequence can include a lead sequence (signal sequence) directing the nascent polypeptide into the pathway of secretion of the host used (col. 4, lines15+). It is well known in the art that Tf domain binds to two iron atoms as evidenced by Prior et al (previously presented, US Patent No. 7,176,278, specially col. 1, lines 59+). Therefore, the prior art of record implicitly or explicitly anticipates the instantly claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yeh et al (US Patent No. 5,665,863) in view of Prior et al (previously presented, US Patent No. 7,176,278).

The instant claims are broadly drawn to a fusion polypeptide comprising a granulocyte colony stimulating factor (G-CSF) domain operably linked to a transferring (Tf) domain, wherein the fusion polypeptide is a recombinant polypeptide, wherein the fusion polypeptide further comprises a secretion signal at the N-terminus and wherein Tf binds to two iron molecules.

The teachings of Yeh et al are summarized as set forth supra. Yeh et al do not specifically teach that Tf domain may bind at least one iron molecule or may bind two iron molecules.

Prior et al teach making fusion of a number of therapeutic proteins with Tf to cross the blood brain barrier (col.1, lines50+). They teach that the Tf portion of the fusion binds to two iron atoms which is required for Tf binding to its receptor on a cell (col. 1, lines 60+).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to make a fusion between G-CSF and transferrin wherein in the G-CSF domain is at the N-terminus of Tf as taught by Yeh et al. Additionally, one would have been motivated to do so because Yeh et al teach making a

fusion between G-CSF and a stabilizing factor such as transferrin. Further, one would have a reasonable expectation of success in making a recombinant fusion between G-CSF and Tf because Yeh et al contemplate making such fusion and because Prior et al make number fusion proteins with Tf.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GYAN CHANDRA whose telephone number is (571)272-2922. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gyan Chandra/
Primary Examiner, Art Unit 1646